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Patient-tailored Workflow Patterns from Clinical Practice Guidelines Recommendations

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Abstract

MobiGuide is a project devoted to the development of a patient-centric decision support system based on computerized clinical guidelines for chronic illnesses including Atrial Fibrillation (AF). In this paper we describe the process of (1) identifying guideline recommendations that will require patients to take actions (e.g., take measurement, take drug), thus impacting patients' daily-life behavior, (2) eliciting from the medical experts the corresponding set of personalized operationalized advices that are not explicitly written in the guideline (patient-tailored workflow patterns) and (3) delivering this advice to patients. The analysis of the AF guideline has resulted in four types of patient-tailored workflow patterns: therapy-related advisors, measurements advisors, suggestions for dealing with interventions that may require modulating patient therapy, and personalized packages for close monitoring of patients. We will show how these patterns can be generated using information stored in a patient health record that embeds clinical data and data about the patient's personal context and preferences.

Keywords:

Clinical practice guidelines, patient-centric care, decision support system.

Introduction and Background

Recommendations reported in Clinical Practice Guidelines (CPGs) are often intended to address care providers more than patients. However, though not explicitly stated, many of these recommendations address patient behavior as well, especially for those chronic illnesses that require the treatment to be continued at home. The process of identifying recommendations that will impact on patient behavior (e.g., "prescribe antiarrythmic drugs") and eliciting from the medical experts the corresponding set of operational advice to direct to the patient (e.g., "remember to take the Amiodarone pill every day 30 minutes before breakfast, i.e., at 7am") is something relatively new and unexplored. Ideally, this advice should consider the patient's personal schedule, influential events, therapies, and personal preferences not accounted for in the guideline.

In the literature, computer-interpretable guidelines (CIGs) have been used to generate patient-tailored educational material [1,2]. For example in [1], the authors generate relevant material, which is then mailed to patients via paper documents. Another interesting aspect of this work is that the personalization of the educational material is driven by the so-called *patient profile*. Such a profile is defined as a patient-specific set of variables that are identified in the CPG as determinant to guide clinical decision. The patient profile is thus defined in an evidence-based manner and is mainly made up of demographic and physical variables. Given the evidence-based nature of the profiles, the only knowledge exploited to create personalized educational material is the one explicitly included in the CPG. The same aspect of considering only explicit knowledge was proposed by [3], where the authors present the development of a patient-centered healthcare process modeling strategy, based on careflows and different knowledge types (medical, organizational, health promotion and illness prevention, customer specific knowledge). The automated generation of patient-tailored electronic care pathways is presented in [4], where the authors derive guideline-based patient-centered care pathways for long-term care. Differently from CPGs, care pathways also take into account organizational settings and are considered as the way CPGs are put into clinical practice. The methodology proposed in [4] relies on knowledge engineering techniques to translate workflows and temporal patterns of CPG into hierarchical task networks to generate patient-tailored care pathways.

What emerges from the literature is that the patient's role in the process of care is becoming more and more crucial, together with the idea of extending CPGs to provide guidance for care outside clinically controlled settings. Such guidance could regard the responsibility of the patient in his medical care as well as monitoring and reacting to changes in patient states. The identification and delivery of patient-oriented recommendations is essential for such goals. The availability of mobile devices to aid patients' self-care is encouraging, and technology has already been shown to help improve adherence to medications at home [5]. To the best of our knowledge, though, the available systems are not developed on CIGs.

In this paper we pursue the main objective of defining a methodology that, starting from an analysis of the CPG, allows identifying those recommendations implying a patient's direct involvement in the continuation of his treatment plan. As we will see, this type of knowledge is often not explicitly written in CPGs, and must be elicited from the medical experts. This results in a set of recommendations specifically directed to the patient and delivered as reminders or educational material. As these recommendations are meant to guide outpatients in the process of managing their own treatment, they may be seen as knowledge-based patient-tailored workflow patterns acting in "parallel" to the guideline(s). The main goal is to improve the patient's compliance with the self-management of his disease.

The MobiGuide project

The idea underlying the methodology presented in this paper arose in the context of the MobiGuide project. MobiGuide is a European funded project carried on by a consortium of 12

partners from several countries in Europe (Italy, Israel, The Netherlands, Spain, and Austria). The project is aimed at developing a knowledge-based patient guidance system based on CIGs and designed for the management of chronic illnesses, including Atrial Fibrillation (AF). The main components of the MobiGuide System are a Decision Support System (DSS) devoted to the representation and execution of CIGs and a Body Area Network (BAN) including a network of sensors and a mobile device (a smartphone) to support telemonitoring of the patient. The data collected by the system are stored in a Patient Health Record (PHR). The main feature of the system is its mobile nature, which allows the monitoring of biosignals that are transmitted to the DSS. The DSS, in turn, analyzes the data, couples them to the clinical history of the patient and, on the basis of the directions established by the physician and the patient during face-to-face encounters, delivers to the patient GL-based recommendations and reminders regarding therapy, lifestyle changes or communication with the care providers. The system is then able to accompany the patient wherever he goes, ensuring a constant application of CPGs also outside the hospital. Of course, the system is also addressed to care professionals. They have the possibility of managing and visualizing patients' data, both those related to the clinical and therapeutic history and those coming from the sensors or manually introduced by the patients in the smartphone. Moreover, they can manage guidelines recommendations coming from the DSS. When a patient becomes eligible for a GL recommendation that has not been previously approved by the care professional and discussed with the patient, the system alerts the care professional, who is then able to examine the recommendation and, if he agrees, to activate respective CIG-based actions for his patient. If for some reason the doctor decides not to accept a specific recommendation, he is also given the possibility of motivating this choice, thus helping to understand the causes of non-compliance.

In the following, we will outline the steps of the methodology for identifying patient-tailored workflow patterns and present some results obtained in MobiGuide by applying the proposed methodology to the guideline for AF [6].

Materials and Methods

The main steps of the methodology presented in this paper are outlined in Figure 1. The first phases (Rectangle 1) are also performed during the process of formalization of a CPG into a CIG. They require the knowledge engineer (KE) to work with clinical experts on the analysis of the guideline and extraction of the relevant recommendations. The following steps require an even closer interaction with clinical experts to elicit tacit knowledge and to create a patient profile template. The method then divides into two parallel branches: one is the most traditional and is directed to the care professional (Rectangle 2), while the second one is the novel approach described in this paper (Rectangle 3), which tailors the GL to the patient.

In the following sections we will detail some steps of the methodology, focusing in particular on Rectangles 1 and 3 in Figure 1 that contain the novelty of the paper. We will not go into the details of Rectangle 2 as it represents a more traditional medical informatics topic.

Analysis of the guideline and extraction of the relevant recommendations

The steps related to the analysis of the CPG and to the extraction of the relevant recommendations are performed by the knowledge engineer with the help of clinical experts at the beginning of the process for converting a CPG to a CIG. To extract patient-tailored parallel workflows from the guideline, though, those steps need to be enhanced. In fact, besides extracting recommendations that are relevant for the physician or other health care professionals' practice, the knowledge engineer is also responsible for detecting those recommendations that might imply advice for the patient, typically to be carried out at home. This is, for example, the case of recommendations related to therapy prescription. They suggest to the physician when, and under what condition, to prescribe a specific treatment. After such prescription is delivered to a specific patient, the patient himself (or his home caregivers) will be responsible for the day-to-day management of his treatment at home. Such recommendations represent the starting point of a process of care (workflow) that is parallel to the guideline and completely patient-centric. The availability of a mobile device able to support the patient in his routine makes it possible to implement such patient-tailored workflow pattern in practice.

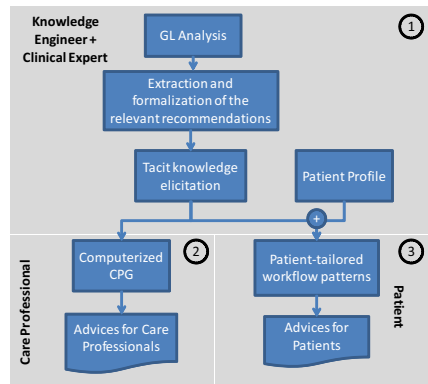

Figure 1 – The methodology followed for patient-tailored workflow patterns identification

Extracting patient-oriented tacit knowledge from CPGs

CPG recommendations can refer to several types of actions, such as therapeutic prescriptions, treatment indications, surgical interventions, laboratory tests, etc.

As a matter of fact, the knowledge surrounding a guideline can be classified into different categories. First of all, there is the knowledge that is explicitly written in the text (explicit knowledge). Second, there is the knowledge that is not written in the guideline, but that doctors use, on the basis of their experience, to deliver clinical care to the patients. This last type of knowledge is known as tacit knowledge [7]. In the health care field, tacit knowledge is a very valuable source of information [8]. The process of acquiring tacit knowledge from clinical experts and making it available as explicit knowledge is known as explicitation. It generally requires a close collaboration between the knowledge engineer and the clinical expert.

To better explain the aforementioned concepts we consider the following recommendation extracted from [6]:

"*Measurement of the heart rate at rest and control of the rate using pharmacological agents (either a beta blocker or nondihydropyridine calcium channel antagonist, in most cases) are recommended for patients with persistent or permanent AF".*

The knowledge explicitly contained in this recommendation suggests the physician to prescribe a therapy for rate control and advise the patient to measure heart rate (HR) at rest. From the first steps regarding the analysis of the guideline, this will be selected as a recommendation that has implications for the patients. From the patient's point of view, we can indeed assume that he will have to regularly monitor his HR, and, secondly, he will have to take the prescribed medications. The knowledge related to the therapy delivery process and to the

frequency of HR measurements, though, is tacitly owned by the physician. He will thus prescribe the final treatment plan on the basis of this recommendation, of the drug summary of product characteristics, and of his experience, which he will try to suit to the patient's personal context. When analyzing this recommendation with an expert cardiologist, we also found out that it can be applied only to patients not suffering from bradycardia (HR<60 bpm). This knowledge (typically contraindications) is not addressed by the guideline, and can be extracted only by relying on clinical experience.

As shown in Figure 1, after the KE has identified all the relevant recommendations, especially focusing on those implying a self-management of the patient back home, a step for eliciting tacit knowledge from the health care experts is necessary. To perform this step, we followed a paradigm similar to the one proposed in [9], centered on the formulation of scenarios to activate an expert's innate tacit knowledge, in contrast to delivering passive interviews to the physicians. In [9], the formulation and delivery of scenarios to the doctors is performed automatically and dynamically throughout the process of knowledge acquisition. In this phase of our research, instead, we deliver scenarios that are manually defined by the knowledge engineer on the basis of the specific recommendations for which he needs to extract the tacit knowledge.

The need for a patient profile

In order to deliver patient-tailored advices during homecare, it is important to take into account a number of factors. First of all there is the patient's clinical history, which in the MobiGuide system is stored in the PHR. Together with this strictly clinical information, though, it is of crucial importance to also store some information related to the personal context of the patient. For this reason we have introduced in the PHR the notion of *Patient Profile* (PP). In this paper we adopt a model of patient profile that is broader than the ones already presented in the CIG-related literature. In fact, we take into account specific information about the home context of the patient, his geographic position, his habits and his preferences.

The knowledge engineer and the clinical expert define the structure of the PP during the design phase of the methodology (Rectangle 1). Then, during a face-to-face encounter between the care provider and his patient, out of a list of potential personal context variables and their possible scale values, the physician characterizes the PP. These context variables were elicited by conducting interviews with 36 healthcare professionals and 14 chronic patients. Working with medical experts, we are extending the CPGs with recommendations relating to specific context values, which take account of the effect of personal context on treatment. We add to CIGs potential generic plans suitable for the personal context relevant to the CPG. For example, for the context of family support that is limited, a generic plan would be composed limiting the amount of physical exercise to moderate exercise not more than 3 times a week and medication treatment relying more on long-acting drugs. Given these generic plans, when a doctor personalizes the MobiGuide care plans for his patient, he defines the relevant PP and instantiates the generic care plans with specific quantities for doses, etc. The doctor instantiates plans for the steady-state context of the patient and for recurring temporary context. The patient may then receive from the MobiGuide system personalized recommendations tailored to his steady-state PP, and once he updates his current personal state to one of the predefined recurring contexts, the recommended plans are adjusted. The PP also includes patient habits and preferences regarding the timing of meals, type of drug administration (e.g., i.v. vs. oral administration) and preferences related to alerts triggering (these are in general shared between patient and care providers). The responsibilities, authorization, and involvement of unofficial caretakers (family members, live-in aids) can also be specified.

Setting up patient-tailored workflow patterns and advice to the patients

After setting up the knowledge engineering process to extract the explicit and the tacit knowledge related to the patient implementation of the CPG recommendations, the last step is to define the system through which such recommendations will be delivered to the patient. Reminders were shown to be one of the most effective interventions for health care professionals to improve clinical practice [10]. In MobiGuide we chose to use the same system to implement patient-tailored workflow patterns. After these recommendations are properly formalized, a set of reminders will be sent to the patient on the basis of his profile to guide him through his workflow. Patient preferences regarding frequency of the alerts and thresholds on the number of non-compliances triggering an alert may help limit the phenomenon of alert fatigue.

In the next section we will present the results obtained so far for the AF guideline. The full implementation of the guideline into the DSS still has to be performed, but a prototypical version of the mobile application exploiting a selection of recommendations was developed during the first project year.

Results

Analysis of the AF guideline led to the extraction of workflow patterns related to several types of recommendations. As each parallel workflow results in the delivery of a set of reminders to the patient, we define these reminders advisors:

- therapy-related advisors, to help the patient complying with his treatment;
- measurements advisors, to remind the patient to take measurements such as heart rate, weight or blood pressure;
- suggestions for dealing with personal situations that may necessitate modulating the patient's therapy
- personalized packages for specific close monitoring and follow-up of patients

Therapy Advisors

As already mentioned throughout the paper, recommendations related to therapy prescriptions have a strong impact on the patient, who is responsible for the management of his therapeutic plan at home. The impact is especially meaningful if the therapy is meant to last for a long time.

Starting from the therapy prescription data structure in the PHR (Table 1), for each patient the DSS will extract a "drug therapy calendar" (Table 2). Each row in Table 1 corresponds to a specific drug prescription. The first row, for example, describes the therapy identified by code Tp1, which is referred to patient Pt1: this subject will have to take 30mg of drug "12345" twice a day from 10/04/2012 to 10/05/2012. Every time the physician prescribes a new therapy, the DSS updates the patient's calendar using information about patient's profile (stored in the PHR) and drugs (stored in the knowledge base).

For each row in Table 1, the system creates a number of rows in the calendar equal to the duration of the therapy properly multiplied by the frequency of administration (in the example of Tp1, two rows per day). Differently from Table 1 where dosages are expressed using the standard measurement units, the patient drug calendar will report dosages in the preferred format for the patient (e.g., "one pill" instead of "30 mg"). Again, as some therapies need to be delivered before or after

lunch, the administration reminder time will be calculated on the basis of the patient's profile, where the usual time for meals during the week and during the weekend are stored: at a suitable time, the DSS will remind the patient to take the drug (e.g. 10 minutes before the therapy administration time). Moreover, it will guide the patient by showing a picture depicting the drug package and, if available, some notes and a video explaining the correct preparation of the drug.

Table 1 – The drug therapy table in the MobiGuide PHR

Ther ID	Pt ID	From	To	Drug Code	Dose	Unit	Freq	Freq Unit
Tp1	Pt1	10/04/2012	10/05/2012	12345	30	mg	2	day
Tp2	Pt1	10/04/2012	10/10/2012	67891	100	mg	1	day

Table 2 – Drug calendar for patient Pt1

PID	Therapy Date	Drug Code	Dose	Administration Time
Pt1	10/04/2012	12345	1 pill	8:30 (after breakfast)
Pt1	10/04/2012	12345	1 pill	21:00 (after dinner)
Pt1	11/04/2012	12345	1 pill	8:30 (after breakfast)
Pt1	11/04/2012	12345	1 pill	21:00 (after dinner)

The parallel workflow pattern includes also a non-compliance monitoring feature to control the day-to-day adherence of the patient to therapy. To this end, the patient can indicate whether he has taken the medication or not, and will be asked to provide a motivation in the case he does not comply with the prescription. In case the drug code reported in the therapy calendar identifies a medication that does not tolerate non-compliance (e.g., an anticoagulant), the DSS will generate a special alert if a patient declares he has not taken the pill, e.g. "The anticoagulation therapy must not be interrupted. If you have specific motivations please call your doctor." Non-compliance cases are then classified according to motivation (drug side effects, drug unavailable, etc.). This is useful for rating the severity of the non-compliance itself. For example, after a given number of non-compliance cases due to a side effect, a message must be sent to the nurse/physician.

Measurements Advisors

The AF CPG suggests the periodical evaluation of some measurements. As the MobiGuide project will provide the patient with a set of devices able to take those measurements, the management of this procedure is a responsibility of the patient. We have thus thought of the Evidence-based Measurements Advisor workflow pattern. As in the case of drugs, a measurements calendar will be filled in by the DSS, taking information from the "Measurements Recommendations" table in the PHR, which has a structure similar to the Therapy table. Table 3 reports an example of such calendar. When the time comes to take a specific measurement, the patient will receive an alert on his smartphone. On the basis of personalized thresholds reported in the patient profile and defined by the physician during a visit (columns 5 and 6 in Table 3), an alert will also be sent back to the nurse/physician when a parameter exceeds one of those thresholds. The source of the measurement (e.g., BAN or manual input) is recorded, and also in this case a compliance detector will be installed on the smartphone. Once non-compliance is detected, a reminder is sent to the patient to solicit the measurement and to the nurse/physician when a number of consecutive non-compliances occur. Table 4 reports the list of the measurements that need to be taken by an AF patient, together with the guideline text where the recommendation is reported.

Table 3 – Measurements calendar for patient Pt1

PID	Measure	Date	Time	Alert Min	Alert Max
Pt1	Weight	03/12/2012	7:00	55	72
Pt1	INR	03/12/2012	12:00	2.5	3.5
Pt1	Syst BP	03/12/2012	7:00	90	130
Pt1	Diast BP	03/12/2012	7:00	40	100
Pt1	INR	10/12/2012	12:00	2.5	3.5

Among measurements, one that has a strong relevance for AF is Heart Rate (HR). As shown in Table 4, there exist many points in the CPG where monitoring of HR is suggested. In the workflow pattern related to this recommended measurement, HR will be managed through a set of specific recommendations. It will be monitored using the BAN sensors and according to the schedule set by the physician. If, during the monitoring, HR exceeds the maximum patient-specific threshold, the patient will be advised to take a rest or to sit down.

Table 4 – Guideline Recommendation Explicitly Suggesting Monitoring Actions

Measure	Guideline Text (knowledge source)
INR	*INR should be detected at least weekly during initiation of therapy and monthly when anticoagulation is stable*
Blood Pressure	*Blood pressure control may become an opportune strategy for prevention of AF*
Heart Rate (HR)	*Measurement of the HR at rest and control of the rate using pharmacological agents […] are recommended for patients with [...] AF*
	Criteria for HR control vary with patient age but usually involve achieving ventricular rates between 60 and 80 bpm at rest and between 90 and 115 bpm during moderate exercise.
	The HR should be monitored at approximately weekly intervals by checking the pulse rate, using an event recorder, or reading ECG tracings ...
Weight	*[…] These findings suggest a physiological link between obesity, AF, and stroke and raise the intriguing possibility that weight reduction may decrease the risk of AF*

Interventions external to the GL or personal context that require modulating patient's therapy or generating alerts

An important set of recommendations that require the activation of a patient-tailored workflow pattern is the one related to the events that might necessitate modulating the patient's therapy, with particular attention to Oral Anticoagulant Therapy (OAT). One of the most severe consequences of AF is the risk of stroke. For this reason, the majority of AF patients undergo OAT at least for three or four weeks after an AF episode. For patients who have a high-risk profile this therapy is often for life. As patients under OAT show an increased risk of bleeding, there are some procedures that require particular caution and ultimately suspension of OAT. The guideline recommendations dealing with these situations are listed in Table 5. This set of recommendations has been identified as potentially interesting to generate a parallel workflow pattern. When eliciting from the clinical experts the knowledge related to the type of procedures that might carry a risk of bleeding (not com-

pletely specified in the guideline text), we found out that, besides surgical interventions or diagnostic procedures, also less invasive settings like an intervention by the dentist or a pedicure might carry substantial risk. This parallel workflow will be implemented in the smartphone through a personal calendar where the patient will be able to record his appointments and events. The DSS will be able to recognize a set of codified events carrying risk of bleeding. In the presence of one of these events, it will be responsible for sending out a reminder to the patient to talk with his doctor to define the OAT administration regime during the days around that particular event. For the correct functioning of this parallel workflow, it is very important to have an updated calendar, once every month an alert will be sent to the patient reminding him to update the calendar. In order to avoid burdening the patient, this alert could be sent only if the calendar is empty. Personal context variables that may affect care recommendations include among others the patient's ability to comply with treatment, the ability to maintain routine diet, routine daily activities, time required to reach the medical center, support level (from family members or live-in help), exercise level. So far, the elicited context variables in the PP that affect recommendation plan for AF patients include daily routine, diet routine and communication level. These impact the recommended physical activity routine, measurement schedule and amount of long-acting medications.

Table 5 – Guideline Recommendations Explicitly Referring to Interventions that might require modulating OAT

GL Reference	Recommendation Text
8.1.4. #4 Preventing Thrombo-embolism CLASS IIa	*In patients with AF who do not have mechanical prosthetic heart valves, it is reasonable to interrupt anticoagulation for up to 1 wk without substituting heparin for surgical or diagnostic procedures that carry a risk of bleeding.*
8.1.4. #2 Preventing Thrombo-embolism CLASS IIb	*When surgical procedures require interruption of OAT for longer than 1 wk in high-risk patients, unfractionated heparin may be administered or low-molecular-weight heparin given by subcutaneous injection, although the efficacy of these alternatives in this situation is uncertain.*

Personalized Packages for close monitoring of patients

In collaboration with the medical experts, we defined a set of personalized packages that care providers can activate whenever they need to monitor some patient-specific parameters (e.g., activating 48h holter ECG anytime the patient undergoes a therapy change). These packages can be activated on the basis of some context that might temporarily recur during patients' care. Examples of such situations are new therapy activations or therapy suspension, the onset of new symptoms or the need to follow-up on specific patient's variables. Moreover, they meet the needs of the physicians who can be more interested in receiving notifications in some specific situations than in others. The process of externalizing patient-related implicit knowledge from the CPG can help also to detect and introduce some educational tips for the patients: these can be some interesting material for the patient to read on demand.

Conclusions

In this paper we have presented the process of extracting a set of patient-tailored workflow patterns from physician-oriented CPG recommendations. We have underlined the importance of considering the patient profile in building up patient-specific recommendations. The work done in AF underlines the importance of considering patient-specific knowledge implicitly included in CPGs with the aim of creating a system as patient-oriented as possible. This effort could also be useful to address issues such as feasibility, plausibility, acceptability, transferability and sustainability, which are critical for the success of CPG implementation [11].

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